APPENDIX A: 510(k) Summary

Sponsor/Submitter:	Acclarent, Inc. 1525-B O'Brien Drive Menlo Park, California 94025
Contact Person:	James Patrick Garvey II Sr. Manager, Regulatory Affairs Phone: (650) 687-4807 Fax: 650-687-4847
Date of Submission:	July 31, 2013
Device Trade Name:	Acclarent Cyclops Multi-Angle Endoscope
Common Name:	Endoscope
Device Classification:	Class II
Regulation Number:	21 CFR 874.4760
Classification Name:	Nasopharyngoscope (flexible or rigid) and accessories
Product Code:	EOB
Predicate Devices:	Acclarent Cyclops Multi-Angle Endoscope (K110097) Entellus Medical FinESS Endoscope (K102366)
Device Description:	The Acclarent Cyclops Multi-Angle Endoscope is a 4.3 mm rigid unchanneled endoscope that has the capability of varying direction of view from 10° to 90°, which is altered by the direction of view dial. The direction of view is indicated by visible markings on the scope body. Cyclops provides a 55° field of view and a depth of focus from 5 mm to 40mm. The device shaft can also rotate 320° to allow for visualization of structures without rotating the device; this is controlled by the shaft rotation dial. Small rare-earth permanent magnets are incorporated into the proximal scope control body ≤ 10 gauss at 2cm) and drive the change in the direction of view. A standard eyepiece located on the proximal end of the device is compatible with a standard camera coupler. The light post on the subject device is compatible with an ACMI light source. There are two stainless steel adapters that accompany the Acclarent Cyclops Multi-Angle Endoscope to facilitate connection with Wolf or Storz/Olympus medical light sources. The adapters connect to the light post. The Acclarent Cyclops Multi-Angle Endoscope is a reusable device and must be cleaned and sterilized or subjected to High Level Disinfection according

to the user manual prior to every use.

Indications for Use:

The Acclarent Cyclops Multi-Angle Endoscope is intended to provide an endoscopic means to view the nasal cavity and nasopharynx.

Technological Characteristics:

Attribute	Predicate Device Acclarent Cyclops Multi-Angle Endoscope	Subject Device Acclarent Cyclops Multi-Angle Endoscope
510(k) number	K110097	TBD
Model Number	CYE002	Same
Rigidity	Rigid	Same
Viewing Optics	Lens (Sapphire cover)	Same
Depth of View	5-45 mm	Same
Field of View	55°	Same
Direction of View	10° to 90°C	Same
Shaft Body Diameter	4.3 mm	Same
Working Length	6.89 inches (175mm)	Same
Magnetic Strength	≤10 gauss at 2cm	Same

Performance Data:

Reprocessing and sterilization testing met all acceptance criteria.

The sterilization process for the Cyclops Multi-Angle Endoscope has been validated and demonstrated a sterility assurance level of 10^{-6} when the device is sterilized via either steam or STERRAD methods. The method used for steam and STERRAD

sterilization validation was overkill (half-cycle approach) in a fixed chamber. The Cyclops Multi-Angle Endoscope has also been validated to be high level disinfected using either 0.55% *ortho*-Phthalaldehyde (Cidex OPA®) or 2.4% glutaraldehyde (Cidex®) solutions.

Clinical data were not necessary for the Cyclops Multi-Angle Endoscope. The testing data demonstrate that the device performs as intended.

Summary of Substantial Equivalence:

The Acclarent Cyclops Multi-Angle Endoscope is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 24, 2014

Acclarent, Inc.
James Patrick Garvey II
Sr. Manager, Regulatory Affairs
1525-B O'Brien Drive
Menlo Park, California 94025

Re: K132433
Trade/Device Name: Acclarent Cyclops Multi-Angle Endoscope
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOB
Dated: March 26, 2014
Received: March 27, 2014

Dear Mr. Garvey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132433

Device Name: Acclarent Cyclops Multi-Angle Endoscope

Indications for Use:

The Acclarent Cyclops Multi-Angle Endoscope is intended to provide an endoscopic means to view the nasal cavity and nasopharynx.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

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